DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Seattle District
Pacific Region
22201 23rd Drive SE
Bothell, WA 98021-4421

Telephone: 425-486-8788
FAX: 425-483-4996

93491d

August 29, 2002

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

In reply refer to Warning Letter SEA 02-61

Andy J. Lanting, Owner
Pine View Dairy
15121 23rd Avenue Northeast
Arlington, Washington 98223

WARNING LETTER

Dear Mr. Lanting:

An investigation at your dairy located at 15121 23rd Avenue Northeast, Arlington, Washington, by our investigators on July 29 and 31, 2002, confirmed that you offered an animal for sale for slaughter as food in violation of Section 402(a)(2)(C)(ii), and 402(a)(4) of the Federal Food, Drug and Cosmetic Act (the Act).

A food is adulterated under Section 402(a)(2)(C)(ii) of the Act if it contains a new animal drug that is unsafe within the meaning of Section 512 of the Act.

- On February 11, 2002, you sold a calf identified with back tag #548 and listed as USDA Case #8-0402-02, Form #411372, for slaughter as human food to [redacted] USDA analysis of tissue samples collected from that animal identified the presence of neomycin in the kidney at 10.04 parts per million (ppm).
- On May 6, 2002, you sold another calf to the same firm identified with back tag #209 and listed as USDA Case #8-0402-02, Form #411385. USDA analysis of tissue samples collected from that animal identified the presence of neomycin in the kidney at 11.17 ppm.

A tolerance of 7.20 ppm has been established for residues of neomycin in the kidney tissue of cattle (Title 21 Code of Federal Regulations 556.430). The presence of this drug in edible tissue from this animal at levels in excess of the established tolerance causes the food to be adulterated.

A food is adulterated under Section 402(a)(4) of the Act "if it has been prepared, packed, or held under insanitary conditions...whereby it may have been rendered injurious to health." As it applies in this case, "insanitary conditions" means that you hold animals which are ultimately offered for sale for slaughter as food under conditions that are so inadequate that medicated animals bearing potentially harmful drug residues are likely to enter the food supply. For example, you lack an adequate system for assuring that animals to which you administer medication have been withheld from slaughter for appropriate periods of time to deplete

potentially harmful residues of drugs from edible tissues. A system must be maintained to assure that all treated animals have treatment records to include:

- the animal's identity;
- the date of treatment;
- the drug administered;
- the dosage administered;
- and the drug pre-slaughter withdrawal time.

The above is not intended to be an all-inclusive list of violations. As a producer of animals offered for use as food, you are responsible for assuring that your overall operations and the foods you distribute are in compliance with the law.

You should take prompt action to correct the above violations and to establish procedures whereby such violations do not recur. Failure to do so may result in regulatory action without further notice such as seizure and/or injunction.

It is not necessary for you to personally ship an adulterated animal in interstate commerce to be responsible for a violation of the Federal Food, Drug, and Cosmetic Act. The fact that you caused the adulteration of an animal that was sold and subsequently offered for sale to a slaughterhouse that ships in interstate commerce is sufficient to hold you responsible for a violation of the Act.

You should notify this office in writing, within fifteen (15) working days of the receipt of this letter, of the specific steps you have taken to bring your firm into compliance with the law. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be completed. Please include copies of any available documentation demonstrating that corrections have been made.

Please send your reply to the Food and Drug Administration, Attention: Lisa M. Althar, Compliance Officer, 22201 23rd Drive SE, Bothell, Washington 98021-4421. If you have questions regarding any issue in this letter, please contact Lisa M. Althar, Compliance Officer, at (425) 483-4940.

Sincerely,

for Charles M. Breen
District Director

Enclosure:
Form FDA 483
FD&C Sections 402(a)(2)(C)(ii) and 402(a)(4)